

IPW —

ATTORNEY'S DOCKET NUMBER: 0492611-0507 (MIT 10396)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Chen *et al.*  
Serial No: 10/674,087  
Filing Date: September 9, 2003  
Title: Compositions and Methods for Delivery of Short Interfering RNA and Short Hairpin RNA

Examiner: Schultz  
Art Unit: 1636

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

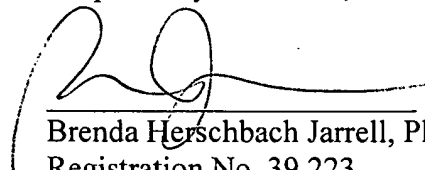
Sir:

**TRANSMITTAL LETTER**

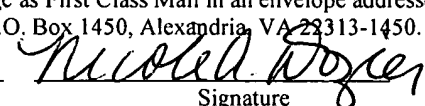
Enclosed are the following documents:

1. Statement under 37 C.F.R. §§ 1.56, 1.97, and 1.98 (6 pages);
2. Form PTO-1449 (2 pages);
3. Cited art (7 references);
4. Credit Card Payment Form (1 page); and
4. Return Postcard.

Respectfully submitted,

  
Brenda Herschbach Jarrell, Ph.D.  
Registration No. 39,223

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Boston, MA 02110  
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Certificate of Mailing	
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December 12, 2006	
Date	Signature
Nicole A. Dozier	
Typed or Printed Name of person signing certificate	

Dated: December 12, 2006

The PTO did not receive the following  
listed item(s) Received as it is



ATTORNEY'S DOCKET NUMBER: 0492611-0507 (MIT 10396)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Chen *et al.* Examiner: Schultz  
Serial No: 10/674,087 Art Unit: 1635  
Filing Date: September 9, 2003  
Title: Compositions and Methods for Delivery of Short Interfering RNA and Short Hairpin RNA

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

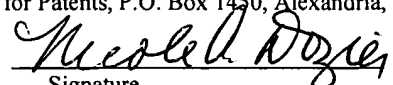
**STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

<b>Certificate of Mailing</b>	
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Date	Signature
Nicole A. Dozier	
Name of Person Signing	

12/19/2006 TBESHAH1 00000008 10674087

01 FC:1806

180.00 OP

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby certifies that *either*:
  - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
  - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☒ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☒ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☒ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included, except for U.S. patents and published U.S. patent applications for which the submission requirements has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☒ A copy of each of the references cited on the attached form PTO-1449 (modified) is enclosed, except for U.S. patents and published U.S. patent applications for which the submission requirement has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☒ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☒ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

It is respectfully requested that:

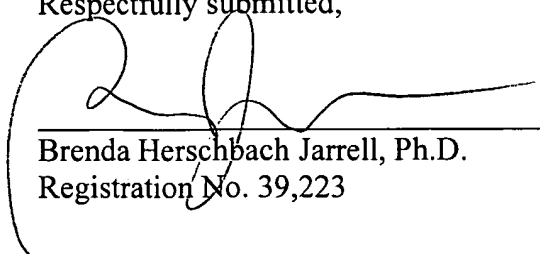
1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Dated: December 12, 2006

Choate, Hall & Stewart, LLP  
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Boston, Massachusetts 02110  
t (617) 248-5000  
f (617) 248-4000

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Brenda Herschbach Jarrell', is written over a horizontal line. The signature is fluid and cursive, with a large loop at the beginning and a long, sweeping tail.

Brenda Herschbach Jarrell, Ph.D.  
Registration No. 39,223

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB number.

Substitute for form 1449/PTO DEC 18 2006 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/674,087
				Filing Date	September 9, 2003
				First Named Inventor	Chen <i>et al.</i>
				Art Unit	1635
				Examiner Name	Schultz
Sheet	1	Of	2	Attorney Docket Number	0492611-0507

U.S. PATENT DOCUMENTS					
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		CA 2 359 180 A1	January 29, 2000	Kreutzer(DE) <i>et al.</i>	Translation	
		EP 1 144 623 B1	January 29, 2000	Kreutzer <i>et al.</i> , Ribopharma AG		

Examiner Signature		Date Considered	
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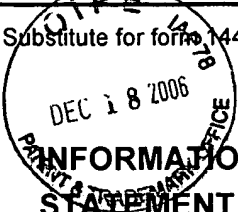
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			<b>Complete if Known</b>	
			Application Number	10/674,087
			Filing Date	September 9, 2003
			First Named Inventor	Chen <i>et al.</i>
			Art Unit	1635
			Examiner Name	Schultz
Sheet 2	Of 2	Attorney Docket Number	0492611-0507	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Behlke, "Progress Toward <i>in Vivo</i> Use of siRNAs", <i>Molecular Therapy</i> , <b>13</b> (4): 644-70, 2006.	
		Griesenbach <i>et al.</i> , "Inefficient cationic lipid-mediated siRNA and antisense oligonucleotide transfer to airway epithelial cells <i>in vivo</i> ", <i>Respiratory Research</i> , <b>7</b> (26), 2006.	
		Tompkins <i>et al.</i> , "Protection against lethal influenza virus challenge by RNA interference <i>in vivo</i> ", <i>PNAS</i> , <b>101</b> (23): 8682-86, 2004.	
		Verma <i>et al.</i> , "Small Interfering RNAs Directed against $\beta$ -Catenin Inhibit the <i>in Vitro</i> and <i>in Vivo</i> Growth of Colon Cancer Cells", <i>Clinical Cancer Research</i> , <b>9</b> : 1291-1300, 2003.	
		Zhang <i>et al.</i> , "Inhibition of respiratory syncytial virus infection with intranasal siRNA nanoparticles targeting the viral NS1 gene", <i>Nature Medicine</i> , <b>11</b> : 56-62, 2004.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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